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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK & CO., INC., ORGANON USA INC., MSD OSS B.V. and ROCHE PALO ALTO LLC, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD, SUN PHARMACEUTICAL INDUSTRIES, INC., and CARACO PHARMACEUTICAL LABORATORIES, INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

PLAINTIFFS MERCK & CO., INC., ORGANON USA INC., MSD OSS B.V., AND ROCHE PALO COMPLAINT

Plaintiffs Merck & Co., Inc. ("Merck"), Organon USA Inc. ("Organon"), MSD Oss B.V. ("MSD Oss"), and Roche Palo Alto LLC ("Roche") (collectively, "Plaintiffs") bring this action for patent infringement against Defendants Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."),

Sun Pharmaceutical Industries, Inc. ("Sun Inc.") and Caraco Pharmaceutical Laboratories, Inc. ("Caraco"), (collectively, "Defendants" or "Sun"). Plaintiffs allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 20-4246 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' highly successful Ganirelix Acetate Injection prior to the expiration of U.S. Patent Nos. 5,757,082 (the "'082 patent") and 6,653,286 (the "'286 patent").

THE PARTIES

2. Plaintiff Merck & Co., Inc. is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Merck is in the business of manufacturing and bringing to market innovative medicines and technologies. Merck is the ultimate parent company responsible for the manufacture and marketing of Ganirelix Acetate Injection. Merck owns both Organon and MSD Oss.

3. Plaintiff Organon USA Inc. is a company organized and existing under the laws of New Jersey, having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Organon is in the business of developing, manufacturing, and bringing to market innovative medicines and technologies. Organon is a wholly-owned subsidiary of Merck & Co., Inc.

4. Plaintiff MSD Oss B.V. is a company organized and existing under the laws of the Netherlands, having a principal place of business at Klooserstratt 6, 5349 AB Oss, Netherlands. MSD Oss is a wholly-owned subsidiary of Merck & Co., Inc.

5. Plaintiff Roche Palo Alto LLC is a company organized and existing under the laws of Delaware. The address of Roche Palo Alto LLC is 1 DNA Way, South San Francisco, California, 94080.

6. Organon is the holder of approved New Drug Application No. 021-057, for Ganirelix Acetate Injection 250 mcg/0.5 mL ("Ganirelix Acetate Injection"). Organon developed and manufactures Ganirelix Acetate Injection, which is provided to inhibit premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation. Ganirelix Acetate Injection is sold throughout the United States.

7. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Michigan, having a principal place of business at 270 Prospect Plains Rd., Cranbury, New Jersey 08512. Upon information and belief, Sun Inc. markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of New Jersey. Upon information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd.

8. Upon information and belief, Defendant Sun Pharmaceutical Industries, Ltd. is an entity organized and existing under the laws of India, with a principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai India 400 059. Upon information and belief, Sun Ltd. develops and markets generic drug products for sale and use throughout the United States, including for sale and use in the State of New Jersey.

9. Upon information and belief, Defendant Caraco Pharmaceutical Laboratories, Inc. is an entity incorporated in Michigan with a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. Upon information and belief, Caraco markets a wide range of generic drug products and regularly conducts business throughout the United States, including in

the State of New Jersey. Upon information and belief, Caraco is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd.

10. Upon information and belief, Sun Ltd. prepared and submitted ANDA No. 20-4246 in collaboration with Caraco and Sun Inc.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Defendants by virtue of the fact that, among other things, each Defendant has continuous and systematic contacts with New Jersey. Defendants have committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

13. This Court also has personal jurisdiction over Sun Inc. because, among other things, it has a principal place of business in the State of New Jersey and thus has submitted itself to the personal jurisdiction of the courts in New Jersey.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

BACKGROUND

15. Women undergoing controlled ovarian hyperstimulation in fertility treatment develop a greater than normal number of eggs during a given cycle. Follicle stimulating hormones ("FSH") are used to stimulate the development of multiple follicles, each of which contains an egg. Normally, ovulation is triggered by a sharp surge in luteinizing hormone. But,

during controlled ovarian hyperstimulation, such "spontaneous" ovulation is undesirable. Ganirelix Acetate Injection is used to prevent these surges, permitting the multiple follicles stimulated by FSH to develop fully.

16. Organon developed and manufactures Ganirelix Acetate Injection pursuant to New Drug Application No. 021-057, which was approved by the FDA. Ganirelix Acetate Injection is indicated for treatment for the inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation, in which a woman's ovaries are stimulated to produce a greater than normal number of follicles. According to the Ganirelix Acetate Injection label (attached hereto as Exhibit A), Ganirelix Acetate Injection is to be administered after FSH therapy has been initiated. The Ganirelix Acetate Injection label indicates that the efficacy of Ganirelix Acetate Injection was evaluated in clinical studies during which exogenous FSH and Ganirelix Acetate Injection were administered daily.

17. Upon information and belief, Sun seeks approval to market a generic version of Ganirelix Acetate Injection for the uses approved by the FDA.

18. United States Patent No. 5,767,082 (the "'082 patent"), entitled "Nonapeptide and Decapeptide Analogs of LHRH Useful as LHRH Antagonists," was duly and legally issued by the United States Patent and Trademark Office on June 16, 1998, to inventors Nestor et al. The '082 patent is owned by Roche by assignment. The '082 patent is exclusively licensed to Organon in the field of Ganirelix Acetate.

19. The FDA-approved use of Ganirelix Acetate Injection is covered by one or more claims of the '082 patent, and the '082 patent was listed in connection with Ganirelix Acetate Injection in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

20. United States Patent No. 6,653,286 (the "'286 patent") entitled "Gonadotropin Releasing Hormone Antagonist," was duly and legally issued by the United States Patent and Trademark Office on November 25, 2003 to inventors Mannaerts et al. The '286 patent is owned by MSD Oss.

21. The FDA-approved use of Ganirelix Acetate Injection is covered by one or more claims of the '286 patent.

22. Upon information and belief, Sun Ltd. submitted ANDA No. 20-4246 under 21 U.S.C. § 355(j)(2) in order to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of Ganirelix Acetate Injection, to be used in infringing manners, prior to the expiration of the '082 and '286 patents.

23. By letter dated July 17, 2012, Defendants notified Plaintiffs that Sun Ltd. had submitted ANDA 20-4246 concerning its proposed drug product of Ganirelix Acetate for injection ("Sun's ANDA product") as required by § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("FDC Act"). *See* 21 U.S.C. § 355(j)(2)(B)(ii).

24. Sun Ltd.'s letter further notified Plaintiffs that Sun Ltd. had filed with the FDA, pursuant to § 505(j)(2)(A)(vii)(IV), a certification with respect to the '082 patent ("Paragraph IV certification"), alleging, along with the letter, that the '082 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Sun's ANDA product.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 5,767,082

25. Plaintiffs reallege and incorporate by reference paragraphs 1–24, above.

26. Roche is the owner by assignment of the '082 patent and has the right to sue for infringement thereof. Organon has an exclusive license to the '082 patent in the field of

Ganirelix Acetate, and has the right to join suits for infringement thereof. A true and correct copy of the '082 patent is attached as Exhibit B.

27. Upon information and belief, Sun's ANDA product, when used as directed, would directly infringe one or more of the claims of the '082 patent.

28. Upon information and belief, Sun's submission of ANDA No. 20-4246 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Sun's ANDA product before the expiration of the '082 patent constitutes an act of infringement of one or more claims of the '082 patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sun's ANDA product would infringe or contribute to or induce infringement of one or more claims of the '082 patent.

30. Upon information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 20-4246.

31. Upon information and belief, immediately upon approval of ANDA No. 20-4246, Sun will infringe the '082 patent by making, using, offering to sell, selling, and/or importing Sun's ANDA product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-4246 shall be no earlier than the expiration date of the '082 patent.

32. Upon information and belief, the use of Sun's ANDA product constitutes a material part of at least one or more claims of the '082 patent; Sun knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '082

patent; and Sun's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

33. Upon information and belief, the offering to sell, sale, and/or importation of Sun's ANDA product would contributorily infringe one or more claims of the '082 patent.

34. Upon information and belief, Sun has knowledge of the '082 patent and knows that its promotional activities, package insert, and label for Sun's ANDA product will induce use of Sun's ANDA product in a manner that infringes of one or more claims of the '082 patent.

35. Upon information and belief, the offering to sell, sale, and/or importation of Sun's ANDA product would actively induce infringement of one or more claims of the '082 patent.

36. Unless Sun is enjoined from infringing the '082 patent, actively inducing infringement of the '082 patent, and/or contributing to the infringement by others of the '082 patent, Plaintiffs will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 6,653,286

37. Plaintiffs reallege and incorporate by reference paragraphs 1–36, above.

38. MSD Oss is the owner by assignment of the '286 patent and has the right to sue for infringement thereof. A true and correct copy of the '286 patent is attached as Exhibit C.

39. Upon information and belief, Sun's ANDA product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe one or more of the claims of the '286 patent.

40. Upon information and belief, Sun Ltd.'s submission of ANDA No. 20-4246 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Sun's

ANDA product before the expiration of the ’286 patent constitutes an act of infringement of one or more claims of the ’286 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sun’s ANDA product would infringe or contribute to or induce infringement of one or more claims of the ’286 patent.

42. Upon information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sun’s ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 20-4246.

43. Upon information and belief, immediately upon approval of ANDA No. 20-4246, Sun will infringe the ’286 patent by making, using, offering to sell, selling, and/or importing Sun’s ANDA product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-4246 shall be no earlier than the expiration date of the ’286 patent.

44. Upon information and belief, the use of Sun’s ANDA product constitutes a material part of at least one or more claims of the ’286 patent; Sun knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the ’286 patent; and Sun’s ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

45. Upon information and belief, the offering to sell, sale, and/or importation of Sun’s ANDA product would contributorily infringe one or more claims of the ’286 patent.

46. Upon information and belief, Sun has knowledge of the ’286 patent and knows that its promotional activities, package insert, and label for Sun’s ANDA product will induce a

patient or doctor to use Sun's ANDA product in a manner that infringes of one or more claims of the '286 patent.

47. Upon information and belief, the offering to sell, sale, and/or importation of Sun's ANDA product would actively induce infringement of one or more claims of the '286 patent.

48. Unless Sun is enjoined from infringing the '286 patent, actively inducing infringement of the '286 patent, and/or contributing to the infringement by others of the '286 patent, Plaintiffs will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

COUNT III
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,767,082

49. Plaintiffs reallege and incorporate by reference paragraphs 1–48, above.

50. Upon information and belief, if ANDA No. 20-4246 is approved, Sun's ANDA product will be distributed in the United States, including in the State of New Jersey, by or through Sun Ltd. and/or Caraco and their affiliates.

51. Upon information and belief, Defendants know that patients or doctors will use Sun's ANDA product in accordance with the labeling sought by ANDA No. 20-4246 and Defendants will therefore infringe one or more claims of the '082 patent.

52. Upon information and belief, Defendants plan to begin marketing, selling, and offering to sell Sun's ANDA product immediately after the FDA approves ANDA No. 20-4246. Such conduct will constitute infringement of one or more claims of the '082 patent under 35 U.S.C. § 271.

53. Upon information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Sun's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 20-4246.

54. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs, and Defendants, concerning liability for the infringement of the ’082 patent.

55. Plaintiffs will be substantially and irreparably harmed by Sun’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,653,286

56. Plaintiffs reallege and incorporate by reference paragraphs 1–55, above.

57. Upon information and belief, if ANDA No. 20-4246 is approved, Sun’s ANDA product will be distributed in the United States, including in the State of New Jersey, by or through Sun Ltd. and/or Caraco and their affiliates.

58. Upon information and belief, Defendants know that patients or doctors will use Sun’s ANDA product in accordance with the labeling sought by ANDA No. 20-4246 and Defendants will therefore infringe one or more claims of the ’286 patent.

59. Upon information and belief, Defendants plan to begin marketing, selling, and offering to sell Sun’s ANDA product immediately after the FDA approves ANDA No. 20-4246. Such conduct will constitute infringement of one or more claims of the ’286 patent under 35 U.S.C. § 271.

60. Upon information and belief, Defendants’ infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Sun’s ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 20-4246.

61. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants, concerning liability for the infringement of the ’286 patent.

62. Plaintiffs will be substantially and irreparably harmed by Sun’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(1) a declaratory judgment that, under 35 U.S.C. § 271(e)(2)(A), Sun Ltd.’s submission to the FDA of ANDA No. 20-4246 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun’s ANDA product before the expiration of the ’082 patent was an act of infringement of one or more claims of the ’082 patent;

(2) a declaratory judgment that, under 35 U.S.C. § 271(e)(2)(A), Sun Ltd.’s submission to the FDA of ANDA No. 20-4246 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun’s ANDA product before the expiration of the ’286 patent was an act of infringement of one or more claims of the ’286 patent;

(3) a declaratory judgment that Sun’s commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun’s ANDA product would constitute infringement of one or more claims of the ’082 patent;

(4) a declaratory judgment that Sun’s commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sun’s ANDA product would constitute infringement of one or more claims of the ’286 patent;

(5) an order that the effective date of any FDA approval of Sun's ANDA product shall be no earlier than the expiration of the '082 and '286 patents, in accordance with 35 U.S.C. § 271(e)(4)(A);

(6) a permanent injunction enjoining Sun, its affiliates and subsidiaries, and all persons and entities acting in concert with Sun from commercially manufacturing, using, offering for sale, or selling Sun's ANDA product within the United States, or importing Sun's ANDA product into the United States, until the expiration of the '082 and '286 patents, in accordance with 35 U.S.C. § 271(e)(4)(B);

(7) an award of damages or other relief if Sun engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of Sun's ANDA product, or any product that infringes the '082 patent, prior to the expiration of the '082 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(8) an award of damages or other relief if Sun engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of Sun's ANDA product, or any product that infringes the '286 patent, prior to the expiration of the '286 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(9) a declaration that this is an exceptional case, and an award of attorneys' fees to Plaintiffs, in accordance with 35 U.S.C. § 285;

(10) an award to Plaintiffs of their costs and expenses in this action; and

(11) such further and additional relief as this Court deems just and proper.

Dated: August 27, 2012

Respectfully submitted,

By: *s/Donald A. Robinson*

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